



AIDS Research Advisory Committee

Rationale & Draft Concept for Coordinated Clinical Research Networks

Bethesda, Maryland

May 24, 2004





Presentation Goals

- Rationale for DAIDS concept
- Solicit input on ways to improve the plan and still achieve the goals



From Principles to Objectives

- Coordinate leadership of networks
- Increase accountability: network and site levels
- Coordinate development of resource poor sites
- Share laboratory resources and protocols
- Common data elements
- Coordinate specimen management
- Share/standardize training for common needs
- Coordinate product acquisition, distribution & provision
- Inter-network meetings
- Greater efficiency with all resources, human and \$\$



Objectives



Concept

- Link Prevention & Treatment
- Coordinate Network research
- Coordinate and elevate community input
- Link funding to performance at Network level
- Link funding to performance at Site level
- Autonomy of international investigators
- Coordinate resource utilization for greater efficiency, better science
- Single RFA; linked scientific priorities
- Managing Partners Committee
- Community Partners Committee
- Evaluation plan; External Review Groups; DAIDS supplemental funds
- Network supplemental funds
- International site RFA
- Managing Partners; Coordination component of Leadership Group application; Clinical Research Management Support contract; Evaluation plan



NIAID & Partner IC's



Managing Partners Committee

External Scientific Review Groups

Clinical Research Mgmt
Support Contract

Leadership Groups (RFA)



Domestic
Sites (RFA)

International
Sites (RFA)

Community Partners

Evaluation Plan



Leadership for HIV and AIDS Clinical Trials Networks

Leadership Groups

Domestic
Sites (RFA)

International
Sites (RFA)

- **Objectives:**
 - Establish cooperative clinical trials groups
- **Mechanism:** U01
- **Expansion/Renewal:** New
- **First year Total cost:** \$210M - \$280M
- **Duration:** 7 years
- **Number of awards:** 6 - 8



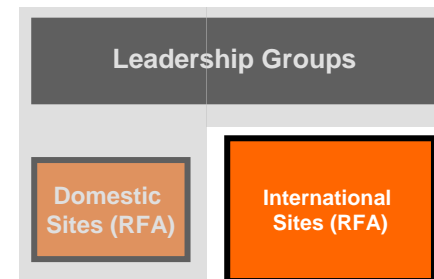
Domestic Sites For HIV Vaccine, Prevention and Therapeutic Clinical Trials

Leadership	Groups
Domestic Sites (RFA)	International Sites (RFA)

- **Objectives:**
 - Establish clinical trial units as components of one or more clinical trials networks
- **Mechanism:** U01
- **Expansion/Renewal:** New
- **First year Total cost:** \$38M - \$100M
- **Duration:** 7 years
- **Number of awards:** 50 - 65



International Sites For HIV Vaccine, Prevention and Therapeutic Clinical Trials



- **Objectives:**
 - Establish international clinical trial units as components of one or more clinical trials networks
- **Mechanism:** U01
- **Expansion/Renewal:** New
- **First year Total cost:** \$12.5M - \$30M
- **Duration:** 7 years
- **Number of awards:** 25 - 40



Leadership Groups RFA

**Translational
Research /
Drug
Development**

**Mother to Child
Transmission**

Microbicides

**Optimization of
Clinical
Management**

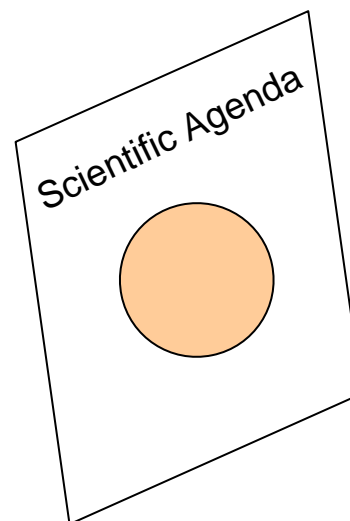
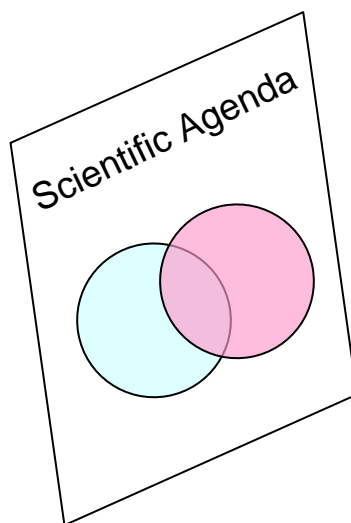
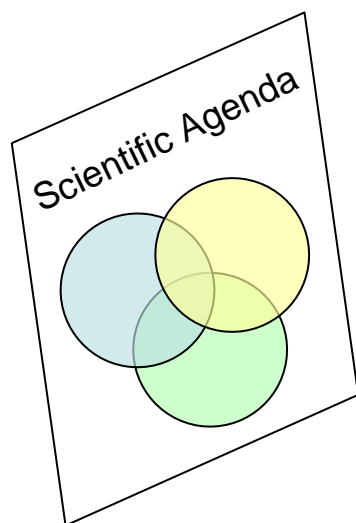
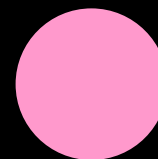
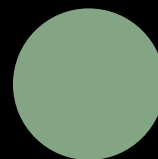
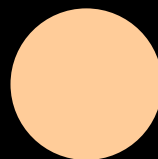
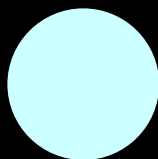
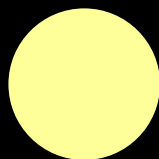
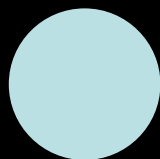
**HIV
Vaccines**

**Prevention of
HIV
Infection**

Populations



Leadership Groups RFA



Applicant Group
#1

Applicant Group
#2

Applicant Group
#3





National Institutes of Health Center for Scientific Review

Form Approved Through 05/2004

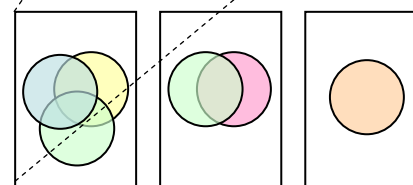
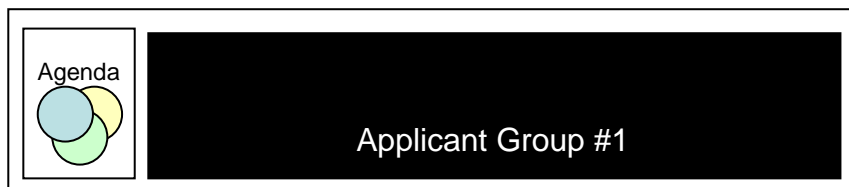
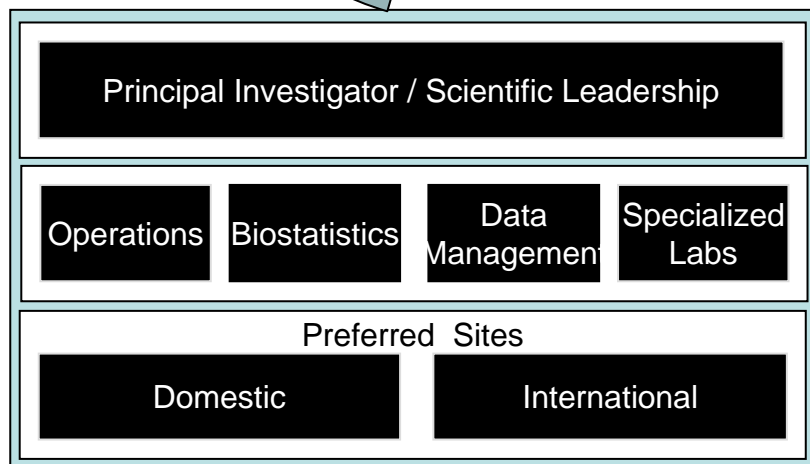
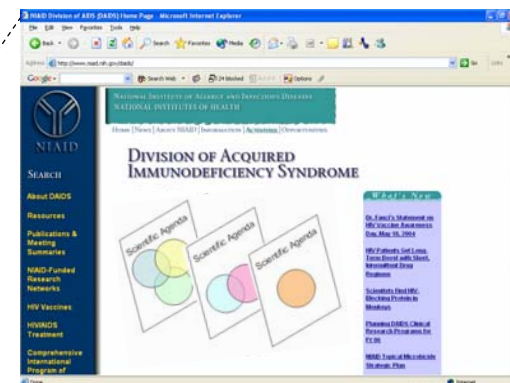
Department of Health and Human Services
Public Health Services

Grant Application
Do not exceed character length restrictions indicated.

1. TITLE OF PROJECT (Do not exceed 56 characters, including spaces and punctuation)

2. RESPONSE TO SPECIFIC REQUEST FOR APPLICATIONS OR PROGRAMS (If "Yes," state number and title)
Number: Title:

3. PRINCIPAL INVESTIGATOR/PROGRAM DIRECTOR



**Successful applicants
become
Leadership Groups**



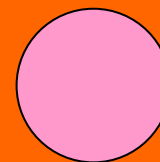
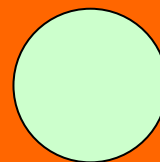
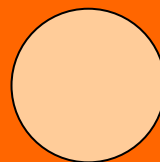
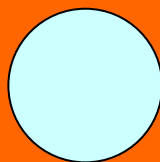
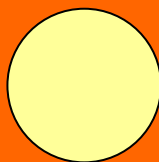
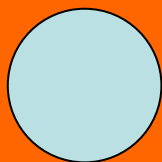
Leadership Groups

**Domestic
Sites (RFA)**

**International
Sites (RFA)**



Domestic Sites RFA



NIAID Division of AIDS (DAIDS) Home Page - Microsoft Internet Explorer

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Address <http://www.niaid.nih.gov/daids/> Go Links

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NIAID

SEARCH

About DAIDS

Resources

Publications & Meeting Summaries

NIAID-Funded Research Networks

HIV Vaccines

HIV/AIDS Treatment

Comprehensive International Program of

NATIONAL INSTITUTE OF ALLERGY AND INFECTIOUS DISEASES
NATIONAL INSTITUTES OF HEALTH

HOME | NEWS | ABOUT NIAID | INFORMATION | **ACTIVITIES** | OPPORTUNITIES

DIVISION OF ACQUIRED IMMUNODEFICIENCY SYNDROME

Scientific Agenda

Scientific Agenda

Scientific Agenda

What's New

[Dr. Fauci's Statement on HIV Vaccine Awareness Day, May 18, 2004](#)

[HIV Patients Get Long-Term Boost with Short, Intermittent Drug Regimen](#)

[Scientists Find HIV-Blocking Protein in Monkeys](#)

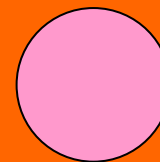
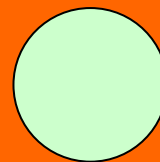
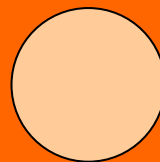
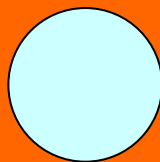
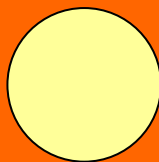
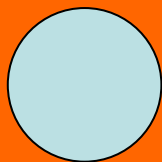
[Planning DAIDS Clinical Research Programs for FY 06](#)

[NIAID Topical Microbicide Strategic Plan](#)

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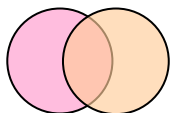


Domestic Sites RFA



Department of Health and Human Services
Public Health Services

Grant Application



- Populations & Trial Capacity
- Partner Sites
- Preferred Network Affiliation

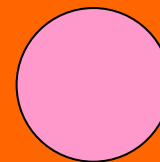
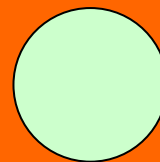
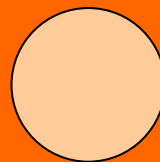
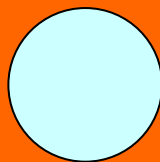
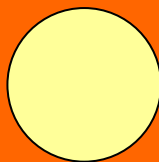
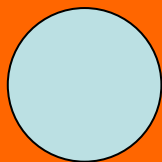
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- Partner Sites
- Preferred Network Affiliation

Site #1



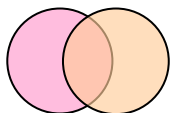


International Sites RFA



Department of Health and Human Services
Public Health Services

Grant Application



- Populations & Trial Capacity
- Partner Sites
- Preferred Network Affiliation
- Capacity Expansion

- Populations & Trial Capacity
- Partner Sites
- Preferred Network Affiliation
- Capacity Expansion

Site #1





Coordinated Clinical Research Networks

LG #1

LG #2

LG #3

Domestic Sites

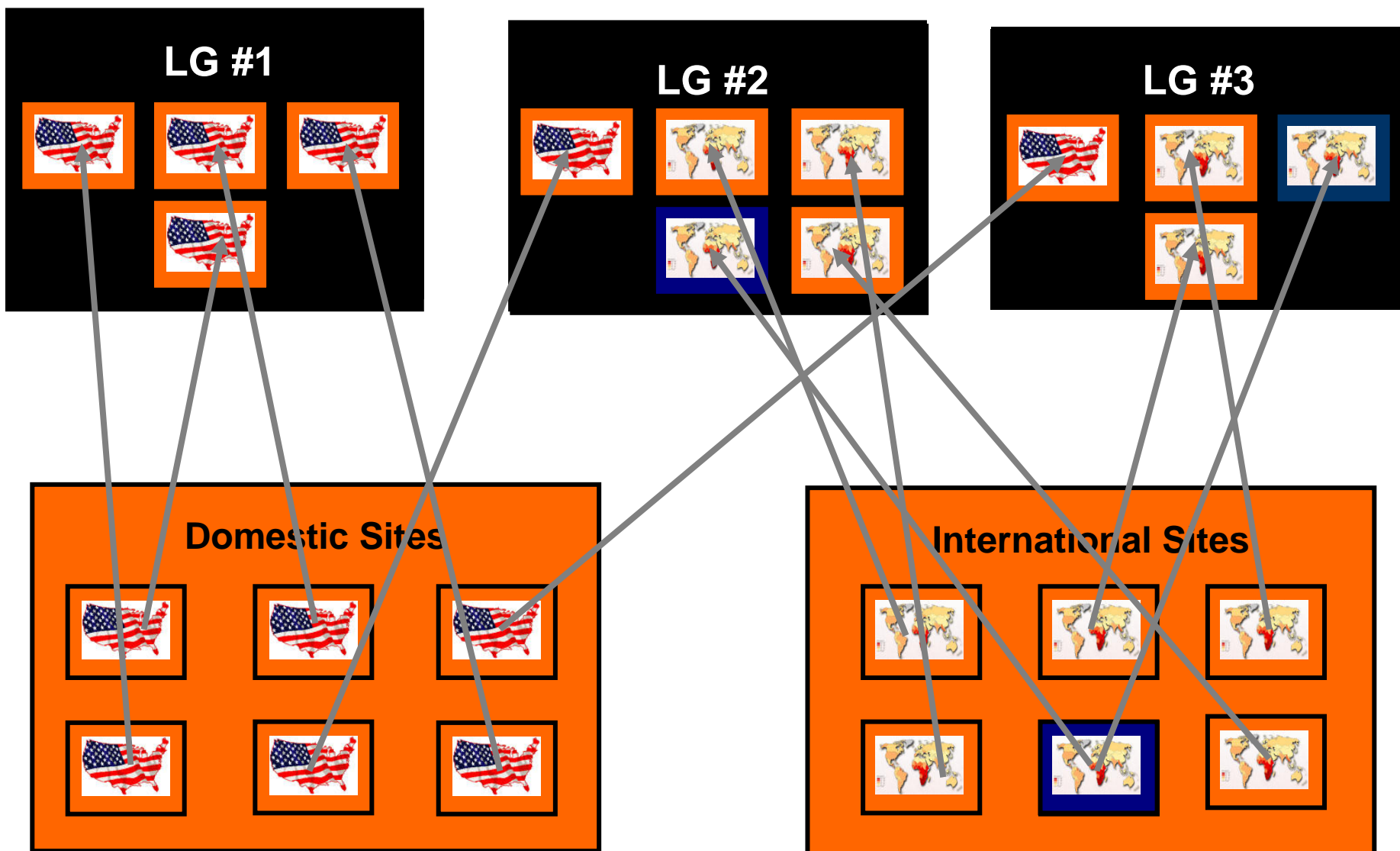


International Sites





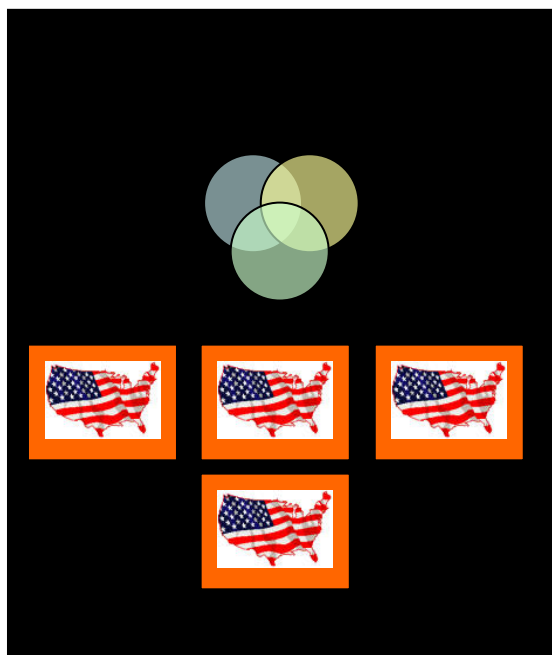
Coordinated Clinical Research Networks



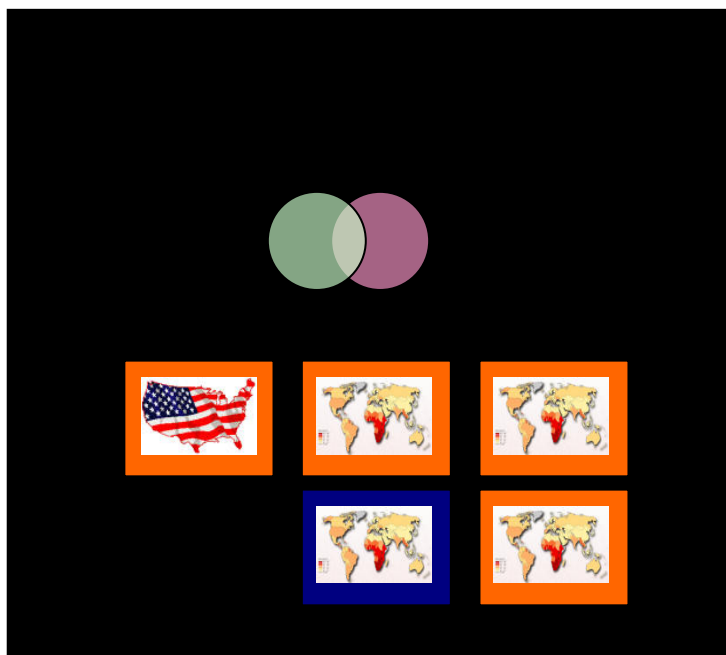


Coordinated Clinical Research Networks

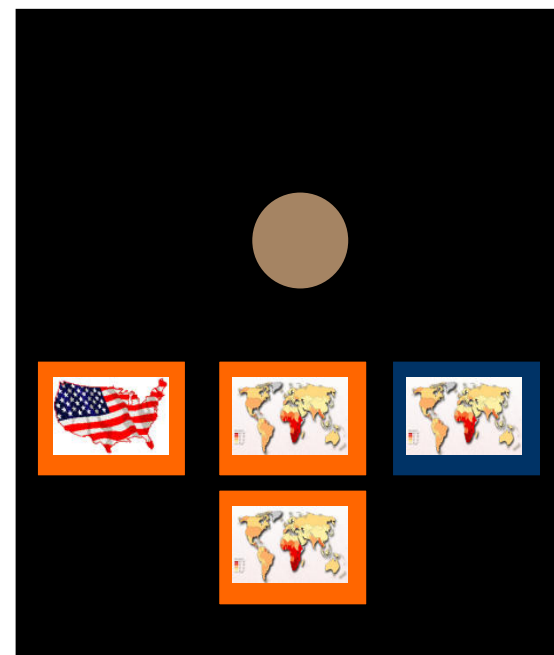
Network #1



Network #2



Network #3





NIAID & Partner IC's

Managing Partners Committee

External Scientific Review Groups

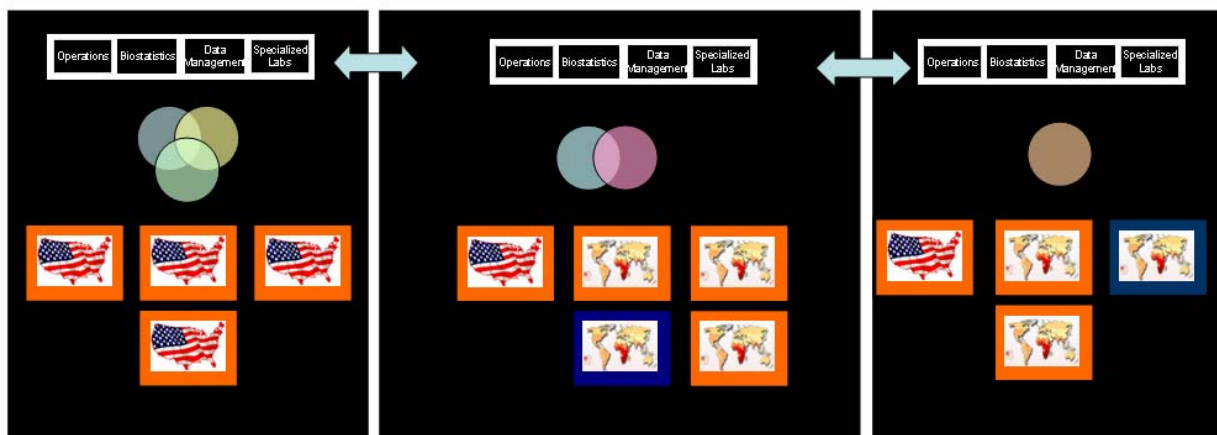
Clinical Research Mgmt
Support Contract

Coordinated Clinical Research Networks

Network #1

Network #2

Network #3



Community Partners

Evaluation Plan



NIAID & Partner IC's

Managing Partners Committee

External Scientific Review Groups

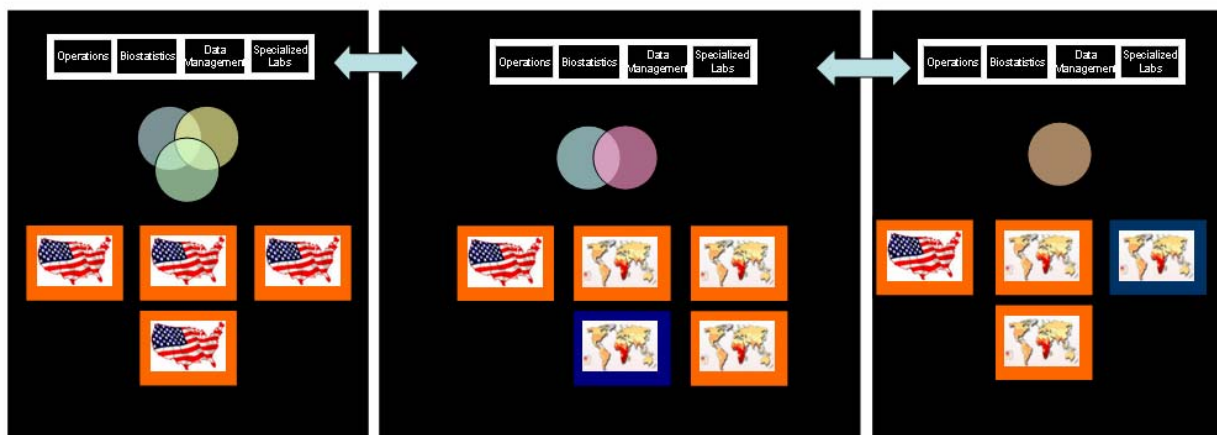
**Clinical Research Mgmt
Support Contract**

Coordinated Clinical Research Networks

Network #1

Network #2

Network #3



Community Partners

Evaluation Plan



Managing Partners Committee

- Coordinate research activities using components of multiple networks
- Increase efficiency by reusing clinical trial infrastructure and resources
- Share plans for protocol development and study conduct across networks
- Promote consistent approaches to network and site evaluation
- Advise DAIDS on adjustments to network sites and/or infrastructure assets
- Establish goals and bylaws within 60 days of Leadership Group awards
- Submit cross network coordination plan for accountability and scientific coordination within a specified time frame of final LG awards
- Membership: PI of each network Core, additional voting members appointed by the Director, DAIDS; one appointed member to serve as Chair of the Managing Partners for a term of one year (renewable)



NIAID & Partner IC's

Managing Partners Committee

External Scientific Review Groups

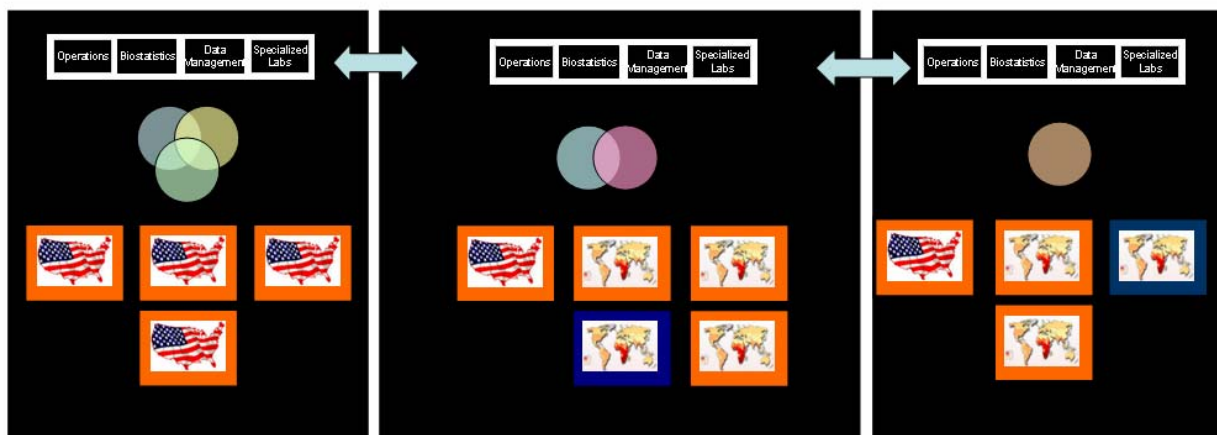
Clinical Research Mgmt
Support Contract

Coordinated Clinical Research Networks

Network #1

Network #2

Network #3



Community Partners

Evaluation Plan



External Scientific Review Groups

- Advisory to Networks, NIAID & IC partners
- Assist in assessing productivity & efficiency
- Advise on changing/competing priorities
- Continuity and flexibility in membership



NIAID & Partner IC's

Managing Partners Committee

External Scientific Review Groups

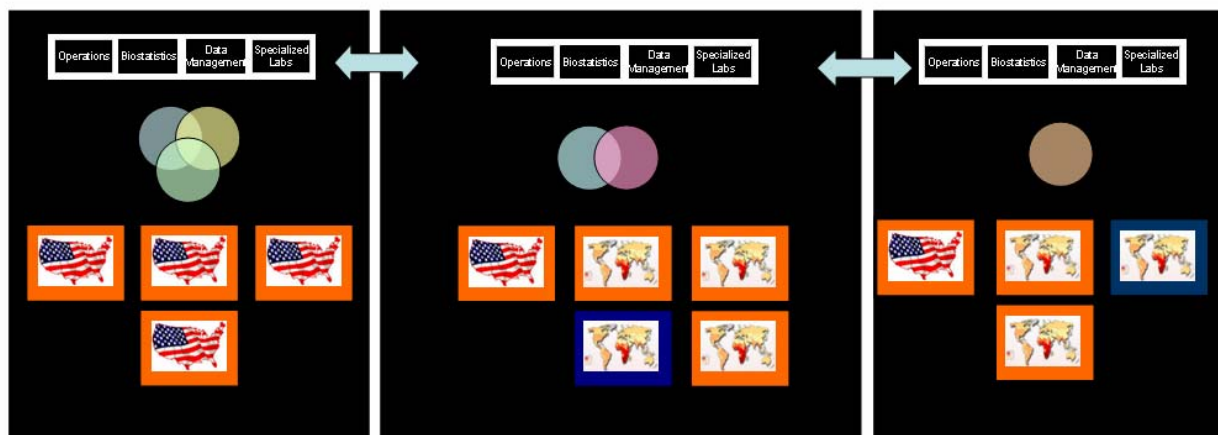
Clinical Research Mgmt
Support Contract

Coordinated Clinical Research Networks

Network #1

Network #2

Network #3



Community Partners

Evaluation Plan



Community Partners

Coordinated leadership to:

- Enhance intra- and inter-network community input
- Identify and develop programs to meet training and support requirements
- Increase resource poor representation and participation
- Address challenges to participation (economic, cultural, language, history, distrust, etc.)
- Enhance framework to better address efforts/activities of CABs



NIAID & Partner IC's

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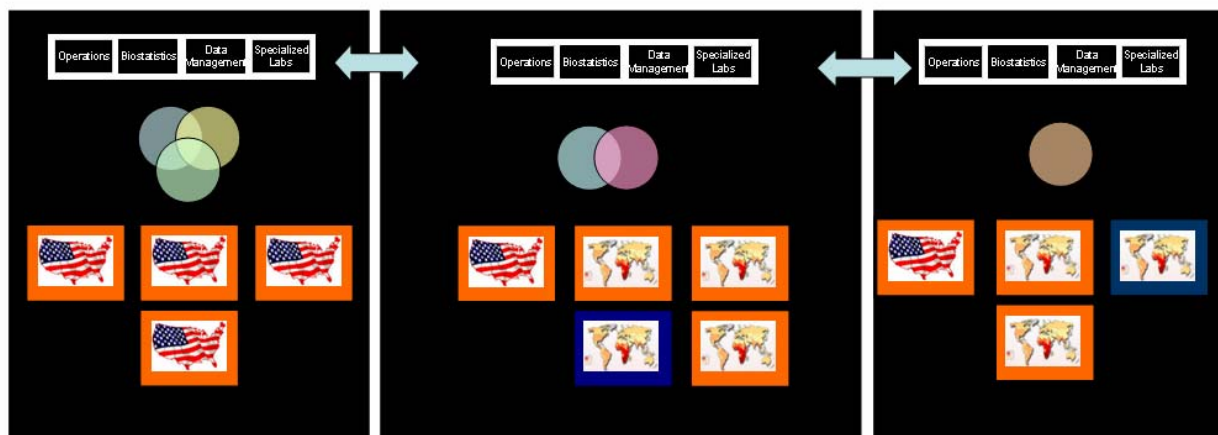
Clinical Research Mgmt
Support Contract

Coordinated Clinical Research Networks

Network #1

Network #2

Network #3



Community Partners

Evaluation Plan



Clinical Research Management Support Contract

Flexible mechanism to support:

- Inter-network coordination
- Community needs and coordination
- Site assessment, planning, management
- Unique needs of institutions/regions
 - Staff recruitment, training, financial mgmt
 - Training
 - Translation
- Sustainable presence for long-term development



NIAID & Partner IC's

Managing Partners Committee

External Scientific Review Groups

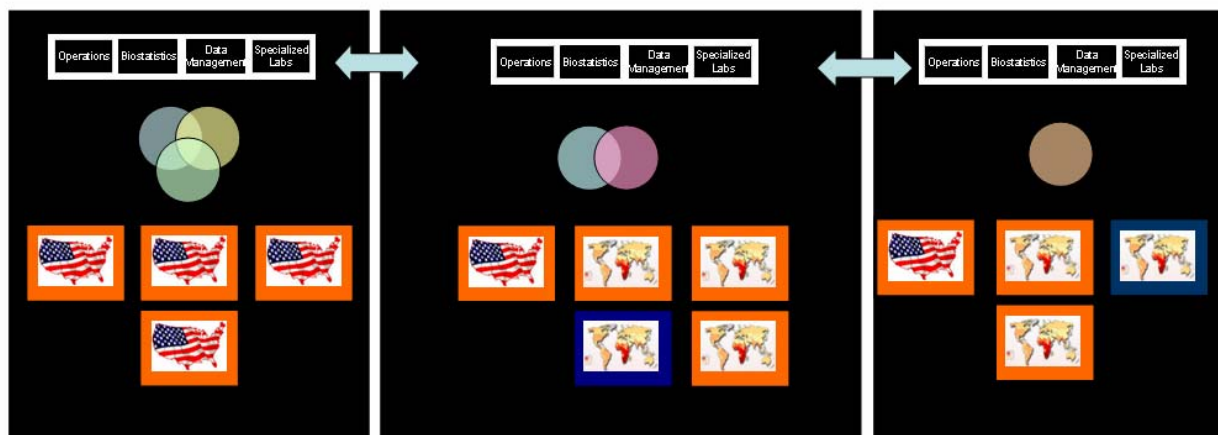
Clinical Research Mgmt
Support Contract

Coordinated Clinical Research Networks

Network #1

Network #2

Network #3



Community Partners

Evaluation Plan



Evaluation Plan

- Evaluate networks individually & collectively
- Defined performance goals, criteria & metrics
- Selected performance areas:
 - Scientific leadership & productivity
 - Operational management & efficiency
 - Quality assurance & Good Clinical Practice
 - Community integration
 - Coordination and partnering
 - Training
 - Communications



NIAID & Partner IC's

Managing Partners Committee

External Scientific Review Groups

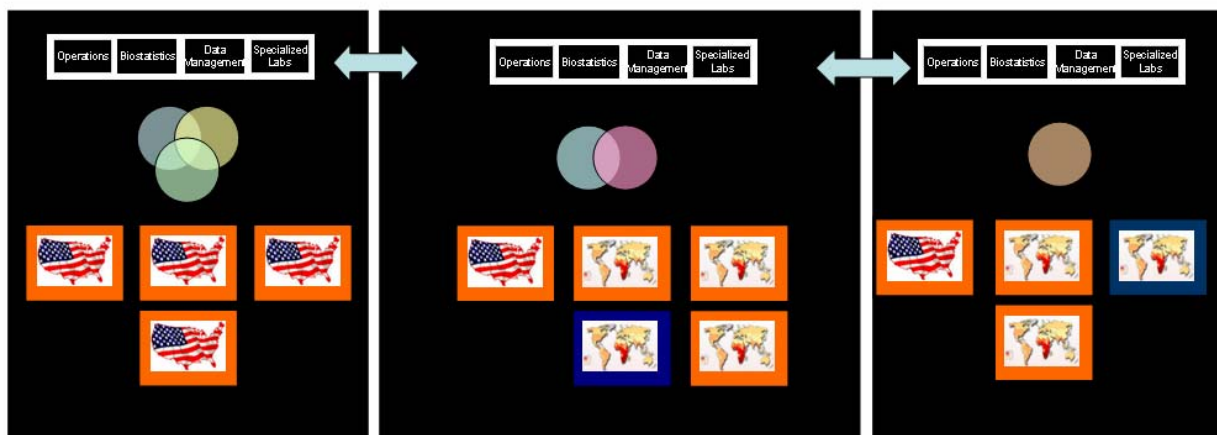
Clinical Research Mgmt
Support Contract

Coordinated Clinical Research Networks

Network #1

Network #2

Network #3



Community Partners

Evaluation Plan



NIAID & Partner IC's

- Inter-IC partnerships to help address IC mission-specific HIV/AIDS research priorities
- IC partner priorities integrated into RFA's
- IC's with "discrete" scientific priorities and/or limited resources gain access to network(s) to fund projects/protocols that address IC-specific priorities
- IC's with "population"-based research priorities and/or greater resources support network(s) more broadly and projects/protocols that address IC-specific priorities
- Partner IC's represented at all levels



NIAID & Partner IC's

Managing Partners Committee

External Scientific Review Groups

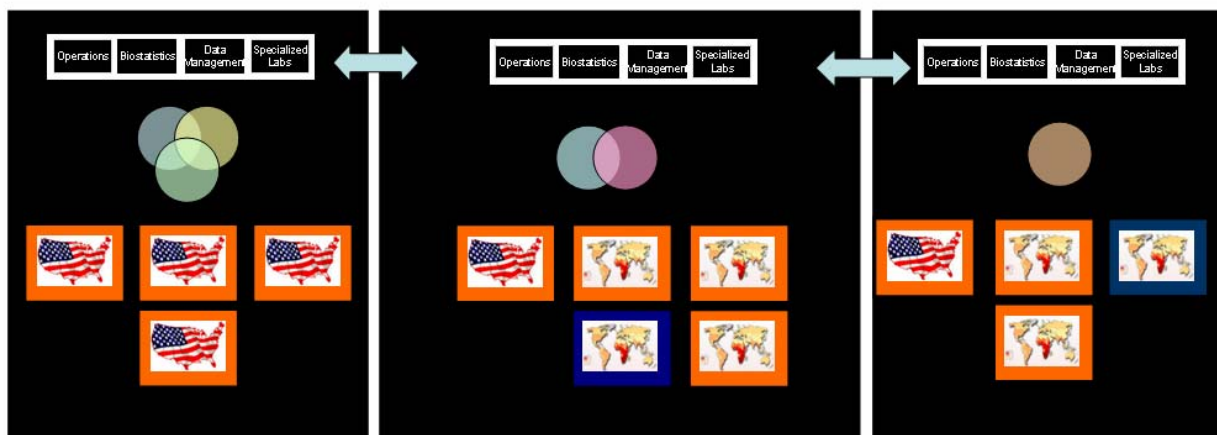
Clinical Research Mgmt
Support Contract

Coordinated Clinical Research Networks

Network #1

Network #2

Network #3



Community Partners

Evaluation Plan



Core vs. Protocol Funding at Network Sites

Core Costs

Personnel

- Site Principal Investigator
- Clinic coordinator
- Community educator
- Administrative support
- Computer support

Supplies (office)

Travel (group meetings)

Other expenses

- Overhead
- CAB support
- Community education
- Equipment maintenance
- Security

Protocol Costs

Personnel

- Lab technician
- Nurse
- Physician/clinician
- Counselor
- Phlebotomist.....

Supplies (lab, clinic)

Travel (sub-sites, protocol meetings)

Other expenses

- Lab testing fees
- Specimen shipping fees
- Participant incentives
- Recruitment/retention



Flexible Site Funding Options

1. Direct NIAID award to institution via Domestic or International Site RFA
2. Partner with other institutions (in-country or international) funded through either site RFA, or other programs (e.g. CIPRA, CFAR, AMC, other agencies, governments, etc.)
3. Partners can be single, multiple (consortia)
4. Rolling admissions
5. Network “core” funding for rapid flexibility; preparation for independent funding



How will Resources be Apportioned between Domestic & International Research?

- Scientific priorities drive the process
- No pre-set allocation of resources for domestic vs. international research
- Where research is conducted depends on the question(s) being asked
 - Single setting
 - Multiple settings, simultaneously and/or sequentially
- Balance can shift over time in response to changing priorities and opportunities



What Differentiates International Network Sites from CIPRA Sites?

CIPRA

- Develops independent research capability and capacity
- Provides a mechanism to prepare for network participation
- Provides resources to conduct independent research on locally relevant questions (e.g., clade distribution, clinical stage distribution)
- Supports basic, epidemiologic and clinical research

Network Sites

- Complement CIPRA by maintaining and expanding clinical site infrastructure within the context of an overall clinical research strategy
- Participation in network clinical trials
- Opportunities to affiliate with multiple networks
- Additional resources for common needs



Non-network clinical research

- Networks cannot do everything (e.g 10,000 patient study for 10 years)
- NIAID will continue to support HIV clinical research outside of network structures
- Balancing Network and Non-network research
- A new funding mechanism will help to ensure:
 - Scientific relevance/contextual prioritization
 - Operational feasibility and quality
- Potential access to DAIDS network resources depending on scientific priority and relevance



Challenges

- Going where the disease is/infections are
- Linking prevention and treatment for research and care
- Long-term follow up & clinical outcomes
- Household-focused approach
- Effective collaborations and linkages (inter-network, intra-NIAID, inter-IC, inter-agency, inter-government, NGO's, charitable organizations, PEPFAR, GFATM, etc.
- Efficiency across the entire effort
- Review



Objectives



Concept

- Link Prevention & Treatment
- Coordinate Network research
- Coordinate and elevate community input
- Performance-based funding
- Autonomy of international investigators
- Coordinate resource utilization for greater efficiency, better science
- Single RFA; linked scientific priorities
- Managing Partners Committee
- Community Partners Committee
- Evaluation plan; External Review; Supplemental funds;
- International site RFA; other flexible funding options
- Managing Partners; Coordination component of Leadership Group application; Clinical Research Management Support contract; Evaluation plan



NIAID & Partner IC's

Managing Partners Committee

External Scientific Review Groups

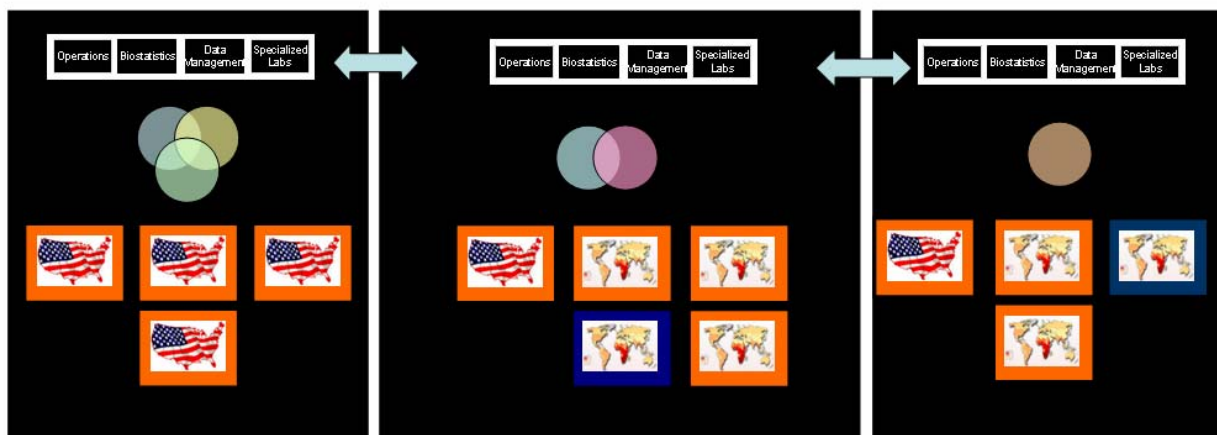
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Community Partners

Evaluation Plan